FDA 510(k) Premarket Notification

K223326 Axiom PSR System

CLEARED

Mar 30, 2023
150 days to decision

K223326 · Product code: **OYK** · Orthopedic
Source: https://www.510kdatabase.net/k223326/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ankle Arthroplasty Implantation System (OYK)
Date received	Oct 31, 2022
Decision date	Mar 30, 2023
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Restor3d**
Location	Durham, NC, US
Contact	Brianna Prindle
510(k) history	11 submissions · 11 cleared · 2020-2025